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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,025	08/26/2008	Matthew Fyfe	NC-10009/US	6838

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OSI PHARMACEUTICALS, LLC  
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Farmingdale, NY 11735

EXAMINER
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SHTERENGARTS, SAMANTHA L

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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06/07/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,025	<b>Applicant(s)</b> FYFE ET AL.
	<b>Examiner</b> Samantha Shterengarts	<b>Art Unit</b> 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 10, 12, 13, 15, and 18 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/>Paper No(s)/Mail Date <u>4/1/2011</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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## **DETAILED ACTION**

### ***Priority***

1. The instant application is a national stage entry of PCT/GB2004/050046, filed December 23, 2004, which claims priority to U.S. Provisional application no. 60/532,370, filed December 24, 2003.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on April 1, 2011 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

### ***Election/Restrictions***

3. Applicant's election without traverse of Group I in the reply filed on April 1, 2011 is acknowledged.

4. As per MPEP 803.02, the Examiner will determine whether the entire scope of the claims is patentable. Applicant's elected species, Example 41, makes a contribution over the prior art of record. Therefore, according to MPEP 803.02: should the elected species appear allowable, the search of the Markush-type claim will be extended. If the search is extended and a non-elected species is not found allowable, the Markush-type claim shall be rejected and claims to the nonelected invention held withdrawn from further consideration. The search of the Markush-type claim has been extended to include the products of the Formula (I).

As a non-elected species has been found not allowable, the Markush-type claims have been rejected and claims to the nonelected invention held withdrawn from further consideration. Since art was found on a nonelected species, subject matter not embraced by the elected

Art Unit: 1626

embodiment or nonelected species is therefore withdrawn from further consideration. It has been determined that the entire scope claimed is not patentable.

### ***Status of the Claims***

5. Currently, Claims 1 and 9-23 are pending in the instant application. Claims 11, 14, and 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention and species. Claims 1, 9-10, 12-13, and 15-18, read on an elected invention and species and are therefore under consideration in the instant application.

### ***Claim Objections***

6. Claims 16 and 17 are objected to for depending on a rejected base claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite and does not define the invention because claims that incorporate by reference the exemplified compounds in the specification are not specific. Statements that incorporate by reference lack any fixed legal meaning and can lead to vagueness and misinterpretation. *Ex Parte Fressola*, 27 U.S.P.Q. 2d 1608 (B.P.A.I. 1993)

8. Claims 1, 9, 12-13, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1626

The definition of variable R2 from claim 1 is cited reproduced below:

R<sup>2</sup> is 4- to 7-membered cycloalkyl substituted by R<sup>3</sup>, C(O)OR<sup>3</sup>, C(O)R<sup>3</sup> or S(O)<sub>2</sub>R<sup>3</sup>, or 4- to 7-membered heterocyclyl, containing one or two nitrogen atoms which is unsubstituted or substituted by C(O)OR<sup>4</sup>, C(O)R<sup>4</sup>, S(O)<sub>2</sub>R<sup>4</sup>, C(O)NHR<sup>4</sup>, P(O)(OR<sup>11</sup>)<sub>2</sub> or a 5- or 6-membered nitrogen containing heteroaryl group;

It is unclear whether "a 5- or 6- membered nitrogen containing heteroaryl group" is an option for variable R2, or whether it is a substituent when R2 is a substituted 4- to 7- membered heterocyclyl ring containing one or two nitrogen atoms. Examiner cannot ascertain the metes and bounds of the invention.

***Claim Rejections - 35 USC § 102***

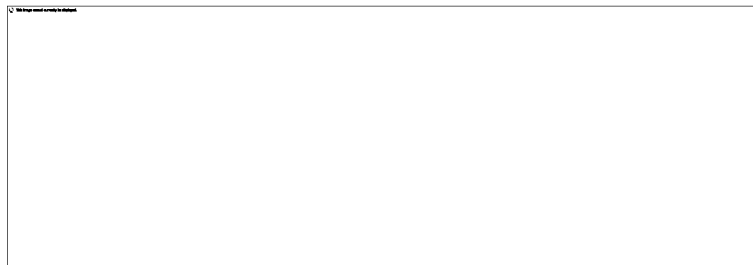
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 9, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent no. 3,647,809 (Reiter et al).

Reiter et al. teaches the following compound



wherein B is –CH<sub>2</sub>–CH<sub>2</sub>– wherein n is

2, R<sub>2</sub> is 6 membered heterocyclyl containing one nitrogen atom, Y is O, X is N, and R<sub>1</sub> is 4-pyridyl substituted with ethyl.

Art Unit: 1626

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 9, 10, 12, 13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaper et al. (WO 2002/012229).

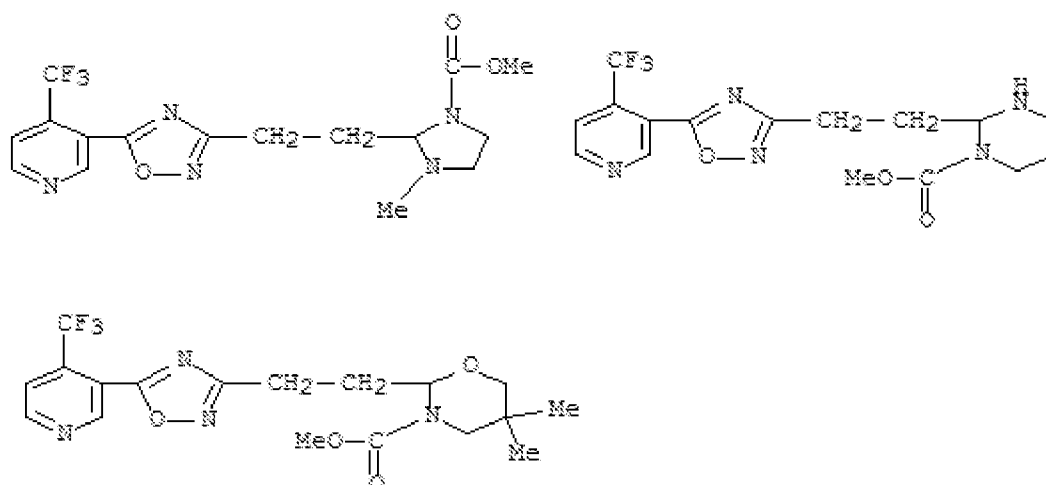
***Determination of the scope and contents of the prior art***

Schaper et al. (WO 2002/012229) discloses obvious variants of the instantly claimed compounds.

***Ascertaining the differences between the instant claims and the prior art***

The following are some of the example compounds taught by Schaper et al.

Art Unit: 1626



wherein the pyridine ring is connected at the 3-position rather than the instantly claimed 4- position.

*Resolving the level of ordinary skill in the pertinent art – Prima facie case of obviousness*

With regards to positional isomers, MPEP 2144.09.II. states, “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In *re Wilder*, 563 F.2d 457, 195USPQ 426 (CCPA 1977).

In positional isomerism, a functional group changes position on the chain or ring. As claimed, these two positional isomers have identical intended uses as well. As stated in *In re Norris* 179 F.2d 970, 84 U.S.P.Q. 458 (C.C.P.A. 1970), a novel useful compound that is isomeric with the prior art compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. In other words, if the positional isomers of the instant application produced unexpected results that would not be obvious to one

Art Unit: 1626

of ordinary skill in the art, they would be patentably distinct; however, there is no evidence of such results in the instant application.

One of ordinary skill would be motivated, from the disclosure in the prior art, to make the modifications required to arrive at the instant invention with reasonable expectation of success for obtaining a compound with the same utility. The motivation to make the change would be to make additional compound for the quoted purpose.

Thus, the instant claims are *prima facie* obvious.

### ***Conclusion***

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/  
Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626